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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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02/16/2001

Yuichi Murayama

P689a

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04/21/2004

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EXAMINER

ODLAND, KATHRYN P

ART UNIT

PAPER NUMBER

3743

DATE MAILED: 04/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/785,743

Applicant(s)

MURAYAMA ET AL.

Examiner

Kathryn Odland

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 March 2004.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1, 7, 8, 11-16, 18, 19, 22, 25-34 and 40-51 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1, 7, 8, 11-16, 18, 19, 22, 25-34, and 40-51 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
10) ☒ The drawing(s) filed on 20 July 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Response to Amendment/RCE***

This is a response to the amendment/RCE dated March 25, 2004. Claims 1, 7, 8, 11-16, 18, 19, 22, 25-34, and 40-51 are pending. The amendments to the drawings to include the "prior art" label are acknowledged.

### ***Response to Arguments***

1. Applicant's arguments with respect to claims 1, 7, 8, 11-16, 18, 19, 22, 25-34, and 40-51 have been considered but are moot in view of the new ground(s) of rejection.

### ***Drawings***

2. The drawings are objected to because they are dark and unclear. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

3. Color photographs and color drawings are acceptable only for examination purposes unless a petition filed under 37 CFR 1.84(a)(2) is granted permitting their use as acceptable drawings. In the event that applicant wishes to use the drawings currently on file as acceptable drawings, a petition must be filed for acceptance of the color photographs or color drawings as acceptable drawings. Any such petition must be accompanied by the appropriate fee set forth in 37 CFR 1.17(h), three sets of color drawings or color photographs, as appropriate, and, unless already present, an amendment to include the following language as the first paragraph of the brief description of the drawings section of the specification:

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The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the Office upon request and payment of the necessary fee.

Color photographs will be accepted if the conditions for accepting color drawings have been satisfied.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

5. Claim 8 recites the limitation "said biocompatible and bioabsorbable protein" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. There has been no previous recitation of a biocompatible and bioabsorbable protein. Thus, it is unclear whether applicant intends the biocompatible and bioabsorbable protein to be the biocompatible and bioabsorbable polymeric material or something other. Any art rejection is as best understood.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 7, 11-14, 18, 22, 25-29, 31-33, 40-46 and 48 are rejected under 35 U.S.C. 102(b) as being anticipated by Strid in US Patent No. 5,386,012.

Regarding claim 1, Strid discloses an apparatus for developing an inflammatory response in a body cavity with cellular manipulation having a

separable implant, at least in part of at least one biocompatible and bioabsorbable polymeric material characterized by its ability to induce controlled inflammation to induce controlled formation of scar tissue in a body cavity to substantially completely occlude the body cavity with out excessive formation of scar tissue, as recited in column 2 and claim 8. With respect to the phrase, "characterized by its ability to induce controlled inflammation to induce controlled formation of scar tissue in a body cavity to substantially completely occlude the body cavity with out excessive formation of scar tissue," applicant is reminded that functional language does not hold patentable weight in apparatus claims. Nonetheless, Strid discloses an implant with a copolymer of poly-L-lactic acid and polyglycolic acid, which would necessarily induce controlled inflammation to induce controlled formation of scar tissue in a body cavity to substantially completely occlude the body cavity with out excessive formation of scar tissue given the structure. Moreover, an endovascular placement device associated with the separable implant adapted to dispose the implant into the body cavity would be necessary and inherent.

Regarding claims 7 and 18, Strid discloses that as applied to claims 1 and 12, as well as, a biocompatible and bioabsorbable polymeric material that is at least one copolymer that is poly-L-lactic acid and polyglycolic acid, as recited in claim 8.

Regarding claim 11, Strid discloses that as applied to claim 1, as well as, a biocompatible and bioabsorbable polymer that promotes cellular manipulation, controlled inflammatory response and vascular healing. Applicant is again reminded that functional language does not hold patentable weight in apparatus claims, Nonetheless, that disclosed by Strid would necessarily achieve this limitation.

Regarding claim 12, Strid discloses a method of causing substantially complete occlusion, of the body cavity by inducing the controlled formation of scar tissue in the body cavity without excessive formation of scar tissue by providing a separable implant having at least one biocompatible and bioabsorbable polymeric material characterized by its ability to induce controlled inflammation; and disposing the implant in the body cavity. See the corresponding rejection for claim 1. Further, where the implant is placed is considered the cavity and given that it occupies the space it can be considered to occlude the space that it takes up.

Regarding claim 13, Strid discloses that as applied to claim 12, as well as, an implant with a noncollagenous protein, as recited in column 4, line 45.

Regarding claim 14, Strid discloses that as applied to claim 12, as well as, an implant that further is at least in part of a growth factor, as recited in column 1, lines 23-26 and columns 3-4.

Regarding claim 22, Strid discloses that as applied to claim 1, as well as, a biocompatible and bioabsorbable polymer that does not elicit foreign body reaction, as recited throughout the specification.

Regarding claims 25, 41, and 42, Strid discloses that as applied to claims 1 and 12, as well as, a biocompatible and bioabsorbable polymeric material that has a selected composition to provide a controlled degradation time to thereby control intravascular inflammatory reactions and degrading faster than by implanted metal coils and providing a stronger inflammatory reaction than metal coils. Again, applicant is reminded that functional language does not hold patentable weight in apparatus claims. Moreover, the scope of the comparison to implanted metal coils is unclear. Thus, given that disclosed by Strid when used to treat blood vessels as disclosed would necessarily provide a stronger inflammatory reaction than with a metal coil.

Regarding claims 26 and 43, Strid discloses that as applied to claims 1 and 12, as well as, a biocompatible and bioabsorbable polymer that regenerates tissue through the interaction of immunologic cells. Again, applicant is reminded that

functional language does not hold patentable weight in apparatus claims.

Nonetheless, given the composition disclosed by Strid, there necessarily would be a regeneration of tissue through the interaction of immunologic cells.

Regarding claims 27 and 44, Strid discloses that as applied to claims 1 and 12, as well as, a biocompatible and bioabsorbable polymer that stimulates cellular infiltration and proliferation in the process of degradation to accelerate fibrosis. Again, applicant is reminded that functional language does not hold patentable weight in apparatus claims. Nonetheless, given the composition disclosed by Strid, there necessarily would stimulate cellular infiltration and proliferation in the process of degradation to accelerate fibrosis.

Regarding claims 28 and 45, Strid discloses that as applied to claims 1 and 12, as well as, a biocompatible and bioabsorbable polymer that would accelerates fibrosis within an aneurysm to more strongly anchor the implant than does metal coils. However, applicant has not positively recited in the claims that this invention is used in an aneurysm. Thus, given that disclosed by Strid when used to treat blood vessels as disclosed would necessarily accelerate fibrosis more than with a metal coil.



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Regarding claims 29 and 46, Strid discloses that as applied to claims 1 and 12, as well as, a biocompatible and bioabsorbable polymer is characterized by generating more connective tissue and a less unorganized clot than metal coils so that an aneurysm in which the implant is disposed is more resistant to a water hammer effect of pulsatile blood than when treated by metal coils. Again, the scope of the comparison with metal coils is unclear and there are no structural features provided to distinguish. Further, applicant has not positively recited an aneurysm. Thus, the scope of the claim is unclear.

Regarding claims 31 and 48, Strid discloses that as applied to claims 1 and 12, as well as, a biocompatible and bioabsorbable polymer that would necessarily restrict aneurysm recanalization by accelerated scar formation when used in treating blood vessels. Further, applicant has not positively recited an aneurysm. Thus, the scope of the claim is unclear.

Regarding claim 32, Strid discloses that as applied to claims 1 and 12, as well as, a biocompatible and bioabsorbable polymer that would necessarily induce organized connective tissue to fill an aneurysm and to retract the aneurysm over time due to maturation of collagen fibers to reduce aneurysm size and decrease aneurysm compression on brain parenchyma or cranial nerves when used in treating blood vessels. Again, functional language does not hold patentable weight in apparatus claims.

Regarding claim 33, Strid discloses that as applied to claims 1, as well as, a biocompatible and bioabsorbable polymer that is less thrombogenic than metal coils and would accelerate aneurysm healing with less thrombogenicity. Again, the scope of the comparison with metal coils is unclear.

Regarding claim 40, Strid discloses that as applied to claim 12, as well as, disposing an implant at the implant site and gradually absorbing the biocompatible and bioabsorbable polymer without leaving residua in the implantation site. The current application specification does not define residua, so the scope of what is considered residua is not limited. Further, given the material disclosed by Strid, the invention of Strid would necessarily achieve this limitation.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 8, 15, 16, 19, 30, 34, 47, and 49-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strid in US Patent No. 5,386,012.

Regarding claims 8 and 19, Strid discloses that as applied to claims 1 and 12.

However, Strid does not recite a biocompatible and bioabsorbable protein that is

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at least one protein selected from the group consisting of fibrinogen, fibronectin, vitronectin, and laminin. On the other hand, it would be obvious to one with ordinary skill in the art to include a protein selected from the group consisting of fibrinogen, fibronectin, vitronectin, and laminin, depending on the implantation site, for they are extraordinarily well known to one with ordinary skill in the art.

Regarding claims 15 and 16, Strid discloses that as applied to claim 14.

Although not explicitly recited growth factors such as endothelial and basic fibroblast are within the scope of the invention and would be obvious to one with ordinary skill in the art.

Regarding claims 30 and 47, Strid discloses that as applied to claims 1 and 12.

However, Strid does not explicitly recite an implant that is a coil. On the other hand, Strid discloses an artificial implant where a coil would fall within the scope of an artificial implant. Thus, it would be obvious to one with ordinary skill in the art to have the implant be a coil.

Regarding claims 49 and 50, Strid discloses that as applied to claim 12.

However, Strid does not explicitly recite an aneurysm. On the other hand, it is within the scope of the invention and would be obvious to one with ordinary skill in the art to employ the implant of Strid in an aneurysm, for treatments of aneurysms are well known in the art.

Regarding claims 34 and 51, Strid discloses that as applied to claims 1 and 12. However, mixture of polyglycolic/poly-L-lactic acid copolymers that is a 90/10 molar ration of glycolic to L-lactic acid has not been explicitly recited. On the other hand, it would be obvious to one with ordinary skill in the art to assure the molar ratio be 90/10.

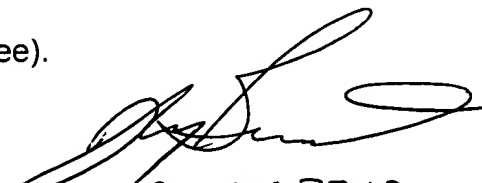
### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn Odland whose telephone number is (703) 306-3454. The examiner can normally be reached on M-F (7:30-5:00) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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